

#### AOSSM SURGICAL OUTCOMES SYSTEM PROGRAM AGREEMENT

This Surgical Outcomes System Program Agreement (this "**Agreement**"), dated as of July \_\_\_\_\_, 2018 ("**Effective Date**"), by and among Arthrex, Inc. ("**Arthrex**"), a corporation organized under the laws of Delaware, and American Orthopaedic Society for Sports Medicine ("**AOSSM**" and with Arthrex each a "**Party**"; collectively, the "**Parties**").

### RECITALS

Arthrex is a developer and provider of the web-based outcome software called Surgical Outcome System ("SOS").

AOSSM is a society made up of leading national and international Orthopaedic surgeons who specialize in surgery of the shoulder and elbow.

AOSSM and Arthrex desire to implement a program ("**Program**") pursuant to which Participating AOSSM Members (as hereinafter defined) would participate in SOS on either a non-research or research basis in accordance with the terms and conditions of either (i) a SOS Participation Agreement for the purposes of health care operations ("**Non-Research Participation Agreement**") or (ii) a SOS Research Participation Agreement ("**Research Participation Agreement**") and Protocol titled "Orthopaedic sports medicine, arthroscopy, and related surgery registry using the web-based Surgical Outcomes System (SOS) (the "**Protocol**") for the purposes as described in the Protocol.

In consideration of the foregoing premises the Parties hereby agree as follows:

1. **DEFINITIONS AND ABBREVIATIONS.** The following terms shall have the meanings ascribed thereto.

Affiliate. An organization controlled by, in control of, or under common control of one of the parties to this Agreement.

**AOSSM Member.** Healthcare providers that satisfy the requirements of membership established by AOSSM.

**AOSSM Member Data.** All data reported in the SOS System that relates exclusively to Data Subjects of Participating AOSSM Members. This includes the methods, analysis and conclusions of the Study, as conducted by a Participating AOSSM Member, and based solely upon data of Data Subjects.

**AOSSM Program Dataset.** A combined subset of two or more Participating AOSSM Member's de-identified AOSSM Member Data. Of note, the AOSSM Program Dataset is a combined subset of the Combined Global Dataset (as herein defined).

**Applicable Laws**. Any foreign or domestic federal, state or local law, statute, code, ordinance, regulation, rule, consent agreement, constitution or treaty of any governmental body (including any Regulatory Agency) applicable to Arthrex, AOSSM, any AOSSM Member or the use or disclosure of any AOSSM Member Data.

Arthrex Results. All methods, analysis, and conclusions of SOS as conducted by Arthrex based on aggregated deidentified SOS System Data including, but not limited to, the de-identified Combined Global Dataset. Any analysis based upon a dataset solely comprised of Participating AOSSM Member Data or the AOSSM Program Dataset is not considered Arthrex Results.

**CFR.** U.S. Code of Federal Regulations.

**Combined Global Dataset.** A dataset aggregated from data reported in SOS by all healthcare providers and facilities participating in SOS (this includes Participating AOSSM Members), which dataset does not contain any subject information which is identifiable under applicable U.S. law.



Data Subject. A patient whose data is uploaded to SOS.

De-Identified Data. Data that satisfies the requirements for recognition as de-identified data pursuant to HIPAA.

FDA. The U.S. Food and Drug Administration and any successor thereto.

**HIPAA.** The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996, along with the implementing regulations found at 45 C.F.R. Parts 160 to 164.

**Personnel.** Employees and contractors of a Participating AOSSM Member who have the requisite expertise to participate in the Participating AOSSM Member's use of SOS.

**Regulatory Agency.** The FDA and any counterpart thereof in other jurisdictions (whether of the United States or any other country, territory, region, or other governmental unit) with competent jurisdictional authority over Arthrex, any Participating AOSSM Member or any party's use or access to Participating AOSSM Member Data.

**SOS Participation Agreement**. Either a Non-Research Participation Agreement or Research Participation Agreement (and Protocol), as applicable.

SOS System. The Surgical Outcomes System.

SOS System Data. Data uploaded to the SOS System.

# 2. SOS-AOSSM PROGRAM PARAMETERS

2.1 AOSSM Program Dataset. Arthrex will make the SOS System available to Participating AOSSM Members (as hereinafter defined) pursuant to the terms of this Agreement and, based on the decision of each Participating AOSSM Member to utilize the SOS System for either operations or research purposes, the applicable Non-Research Participation Agreement or Research Participation Agreement (and Protocol). Additionally, Arthrex agrees to create and make available to Participating AOSSM Members and AOSSM the AOSSM Program Dataset (as herein defined) by combining de-identified Participating AOSSM Members data into a combined subset, provided that the Participating AOSSM Member has signed a Arthrex approved AOSSM Shared De-identified Data Acknowledgment for the inclusion of their de-identified Participating AOSSM Member data in the AOSSM Program Dataset. Such availability will provide each Participating AOSSM Member with access to their own AOSSM Member Data, the AOSSM Program Dataset and the Combined Global Dataset (it being understood that the AOSSM Program Dataset and the Combined Global Dataset would contain no data that is identifiable under applicable U.S. law). AOSSM would own the AOSSM Program Dataset and utilize a data use committee to review and approve Participating AOSSM member use of the AOSSM Program Dataset. As part of this Program, Arthrex will develop and load into SOS, Study Templates (as herein defined) that may be used by Participating AOSSM Members. Participating AOSSM Members and AOSSM would be permitted to export the AOSSM Program Dataset.

2.2 Arthrex Use and Access to AOSSM Member Data and AOSSM Program Dataset. Pursuant to this Agreement, AOSSM hereby grants, and will cause each Participating AOSSM Member to grant, to Arthrex a perpetual non-revocable, non-exclusive, sub licensable, fully-paid, royalty-free license to use AOSSM Member Data. Arthrex may use this information for the disclosure purposes described in a Business Associate Agreement entered into between a Participating AOSSM Member (or other entity contracting on his or her behalf) and Arthrex, and Protocol, if applicable, to make the AOSSM Program Dataset available to AOSSM Members and AOSSM, and to make the Combined Global Dataset available to Participating AOSSM Members, AOSSM and other healthcare providers participating in SOS. This license shall survive termination of this Agreement.



Arthrex will keep a backup of Participating AOSSM Member Data for at least 30 days for auditing and disaster recovery purposes. Arthrex has no further obligation to provide Participating AOSSM Members with access to any such backup.

2.3 Participating AOSSM Members. An AOSSM Member may participate in the Program upon satisfaction of the following criteria ("Participation Criteria"): (i) confirmation by Arthrex that such AOSSM Member's participation in the Program and access to and use of the SOS System are in accordance with all Applicable Laws ("Approved Jurisdictions") and (ii) such AOSSM Member's execution and delivery of either a Non-Research Participation Agreement or Research Participation Agreement (and Protocol), as applicable based on the functionality selected by such AOSSM Member. Any AOSSM Member that satisfies the Participation Criteria shall be referred to herein as a "Participating AOSSM Member"). AOSSM Members who do not sign an Arthrex approved AOSSM Shared De-Identified Data Acknowledgment, allowing the inclusion of their deidentified AOSSM Member Data as part of the AOSSM Program Dataset, shall not be deemed as Participating AOSSM Members under this Agreement. In addition, participation in the Program may be subject to legal and/or ethical requirements or rules imposed in the particular jurisdictions applicable to AOSSM Members. Further, only active AOSSM Members shall be eligible to participate in the Program; AOSSM shall confirm any Participating AOSSM Member's status as an active AOSSM Member upon request by Arthrex and shall also regularly update Arthrex on any Participating AOSSM Member who is no longer an active AOSSM Member. In the event of any inconsistency between the terms of this Agreement and a SOS Participation Agreement, the terms of the relevant SOS Participation Agreement will govern and control. No Participating AOSSM Member shall have the right or authority to modify any of the terms of the Program without the prior written approval of Arthrex and AOSSM.

**2.4 Program Compensation.** AOSSM shall receive access to the SOS System and AOSSM Program Dataset by Participating AOSSM Members in accordance with **Addendum A** attached hereto. The Parties agree that the services provided under this Agreement meet the following requirements of the Personal Services Safe Harbor (42 C.F.R. § 1001.952(d)- under the Anti-Kickback Statute: (1) the aggregate compensation to Arthrex is set in advance and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the Parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs; (2) the Agreement specifies all of the Services to be provided under the Agreement; (3) the services performed under the Agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law; and (4) the services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the Services. Except as otherwise expressly set forth herein, AOSSM and each AOSSM Member shall be solely responsible for all its respective expenses related to its use of the Customized AOSSM Member.

**2.5** Compliance with Laws and Regulations. Arthrex is responsible for storage, maintenance and securing all SOS System Data in accordance with all applicable laws and regulations.

**2.6 Data Export upon Termination.** Upon termination of this Agreement, and subject to the license in Section 2.2, Arthrex will export a file of each Participating AOSSM Member's AOSSM Member Data to such Participating AOSSM Member in a mutually agreeable format and in a secure manner, and then erase all of such Participating AOSSM Member's identifiable data from SOS; provided that, subject to applicable laws, Arthrex may retain a copy of such AOSSM Member Data for archival and dispute resolution purposes, as well as pursuant to the license granted in Section 2.2. Additionally, upon termination of this Agreement Arthrex will export the AOSSM Program Dataset to AOSSM in a mutually agreeable format and in a secure manner from SOS. The deidentified Participating AOSSM Member data will remain in the Combined Global Dataset.

**2.7 Promotion.** AOSSM will promote the SOS System as an outcome registry utilized by AOSSM and its AOSSM Members, and accordingly shall include a reasonable recognition of AOSSM's adoption of the SOS System platform by AOSSM on AOSSM's website (which recognition shall include display of SOS logos



supplied by Arthrex). In addition, any publication of data, reports or analyses derived from AOSSM Member Data and the AOSSM Program Dataset shall contain a reasonable reference to the SOS System as the source of such data.

**2.8 Data Use Committee.** AOSSM will designate a task force that reviews and approves requests by Participating AOSSM Members for use of the AOSSM Program Dataset for presentation and publication purposes. Arthrex shall have reasonable approval rights over the criteria and procedures utilized by such task force in connection with such review and approval.

**2.9 Training.** Arthrex's SOS Team will provide training and consultation through reasonable efforts, in collaboration with the SOS AOSSM Coordinator with respect to use of the SOS System. SOS AOSSM Coordinator will be the main contact for Participating AOSSM Member questions. In addition, Arthrex would make available archived WebEx training sessions as well as a training manual with respect to the SOS System. Further, the Arthrex SOS Team, upon request, would use commercially reasonable efforts to attend AOSSM meetings and events and offer interactive training session with respect to the use of the SOS System.

**2.10** Quarterly Program Feedback. The Parties shall meet at least quarterly via telephone conference to discuss questions, concerns, feedback and supporting needs related to the Program and AOSSM and Participating AOSSM Members' use of SOS.

**2.11** Effect of Termination of Individual SOS Participation Agreements. Termination of the SOS Participation Agreement or the Shared AOSSM Program Dataset acknowledgement by any Participating AOSSM Member does not prevent additional data from being entered into the AOSSM Program Dataset by other Participating AOSSM Members and does not terminate the other Participating AOSSM Members and AOSSM's right to access and use the AOSSM Program Dataset for the remaining term of the AOSSM SOS Program Agreement. Upon termination of the SOS Participation Agreement, the Participating AOSSM Member shall not have access to the AOSSM Program Dataset and no additional Data from such Participating AOSSM Member shall be added to the AOSSM Program Dataset.

# 3. DUTIES

**3.1.** Compliance with Laws and Regulations. AOSSM shall, and shall cause its personnel and take reasonable steps to persuade each Participating AOSSM Member and its personnel to, use the SOS System in compliance with all Applicable Laws.

**3.2. AOSSM SOS Coordinator**. AOSSM will designate an AOSSM SOS Coordinator to liaison with the SOS Business team regarding membership, enrollment and training.

**3.3 AOSSM Member Contact Information.** Telephone numbers, e-mail addresses and other contract information received by Arthrex from the Program shall not be used by Arthrex for any purpose other than in connection with the Program and purposes in connection with this Agreement.

# 4. CONFIDENTIAL INFORMATION

**4.1 Confidential Information, Defined. "Confidential Information**" means, with respect to a Party, any and all non-public information, data or analysis relating to such Party, its business, products, results, methods, invention, plans, strategies or other aspects, including but not limited to, any and all trade secrets, know-how, privileged records or other confidential or proprietary information and data, both technical and non-technical, disclosed in writing or orally, including, without limitation, the existence of and the terms and conditions set forth in this Agreement, other information disclosed by such Party, such Party's other proprietary information of a technical, business or other nature, in any format, written, verbal or electronic, and derivatives thereof.



**4.2 Confidentiality Obligations.** Unless provided with advance written Arthrex consent or to the extent provided pursuant to this Agreement or a SOS Participation Agreement, (a) none of AOSSM, or any AOSSM Member shall publish or disclose, or use for any purpose other than as permitted by this Agreement, any Confidential Information of Arthrex without Arthrex's written consent and (b) Arthrex shall not publish or disclose, or use for any permitted by this Agreement, any Confidential Information of Arthrex without Arthrex's written consent and (b) Arthrex shall not publish or disclose, or use for any purpose other than as permitted by this Agreement, any Confidential Information of AOSSM without AOSSM's written consent.. The obligation of non-disclosure and non-use shall not apply with respect to any portion of the Confidential Information that the receiving Party can demonstrate: (1) is or later becomes generally available to the public by use, publication or the like, through no fault of receiving Party; (2) is obtained from a third party without restriction who had the legal right to disclose the information; (3) is already possessed by the receiving Party, as evidenced by the receiving Party's written records; or (4) is independently developed by the receiving Party, as evidenced by written records.

**4.3 Required Disclosures.** If Party is required to disclose any Confidential Information of the other Party by any law, regulation, subpoena, order, decree, or decision or other process of law, the receiving Party will provide the disclosing Party with prior written notice and a reasonable opportunity to seek a protective order and the receiving Party shall furnish only that portion of such Confidential Information the receiving Party is advised by counsel is required to be disclosed by law.

- 5. PROTECTED HEALTH INFORMATION. AOSSM acknowledges that each Participating AOSSM Member shall be solely responsible for: (i) obtaining any consent, authorization or permission that may be required by the HIPAA Privacy Rule or any other Applicable Laws prior to furnishing Arthrex the Protected Health Information pertaining to a patient; and (ii) and not furnishing to Arthrex any Protected Health Information that is subject to any arrangements permitted or required of such Participating AOSSM Member or any healthcare facility to which such Participating AOSSM Member, "Covered Participants"), including but not limited to, arrangements agreed to by Covered Participants under 45 C.F.R. § 164.522 that may impact in any manner the use and/or disclosure of Protected Health Information by Arthrex under this Agreement or the Data Sharing Agreement(s). Each AOSSM Member will represent and warrant to Arthrex that it has the right and authority to disclose Protected Health Information to Arthrex's use of the Protected Health Information to perform its obligations and provide services to such Participating AOSSM Member, and Arthrex's use of the Protected Health Information to perform its obligations and provide services to such Participating AOSSM Member, and Arthrex's use of the Protected Health Information to perform its obligations and provide services to such Participating AOSSM Member, and Arthrex's use of the Protected Health Information to perform its obligations and provide services to such Participating AOSSM Member, and Arthrex's use of the Protected Health Information to perform its obligations and provide services to such Participating AOSSM Member, and Arthrex's use of the Protected Health Information to perform its obligations and provide services to such Participating AOSSM Member as requested does not violate the Privacy Rule, Facility's privacy notice or any Applicable Law.
- **COMPLIANCE.** Each Party represents and warrants that it shall comply with all Applicable Laws in any 6. jurisdiction applicable to Arthrex, AOSSM or any AOSSM Member, including, without limitation, those that are recognized by the Food and Drug Administration ("FDA"), the Department of Health and Human Services ("HHS"), and the Centers for Medicare and Medicaid Services ("CMS"), which shall include, without limitation, the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), any applicable "exceptions" or "safe harbors" under the Federal Anti-Kickback Statute, any state laws comparable to the Federal Anti-Kickback Statute, as well as anti-corruption laws; the Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations (collectively, "HIPAA"), and any analogous state laws; and the Physician Payment Sunshine Act, 42 USC. § 1320a-7h, and it's implementing regulations. Notwithstanding any unanticipated and unintended effect of any provision of this Agreement, neither Party, by virtue of entering into this Agreement or otherwise, is willfully offering, paying, soliciting or receiving remuneration in return for referring an individual to or from each other for the furnishing of any item or services payable in whole or in part under the Federal Health Care Programs. Each Party represents and warrants that neither it, nor any of its directors, employees, or agents, has ever been barred or excluded from participating in any federal or state health care program, or convicted of a criminal offense with respect to health care reimbursement. Each Party shall immediately notify the other Party if the foregoing representation becomes untrue, or if at any time after the Effective Date of this Agreement it is determined that either Party is in breach of this section, this Agreement shall, as of the effective date of such debarment or exclusion, be automatically terminated.



# 7. INTELLECTUAL AND OTHER PROPERTY RIGHTS

**7.1 Ownership of Certain Data.** Each Participating AOSSM Member shall retain ownership of their AOSSM Member Data in the SOS System. AOSSM shall own all right, title and interest in the AOSSM Program Dataset, subject to the license granted in Section 2.2. Arthrex shall own all Arthrex Results including, without limitation, the Combined Global Dataset, which is de-identified in accordance with HIPAA. Arthrex shall further own all datasets containing data from two or more facilities or health care providers participating in SOS, including datasets containing aggregate de-identified information from two or more facilities or health care providers or health care providers ("global data" or "multiple site data"), and all information and data taken from or derived from these datasets, with the exception of the AOSSM Program Dataset or combined datasets specified in an Arthrex approved Data Sharing Agreement.

**7.2 Ownership of the SOS System.** AOSSM and each Participating AOSSM Member understands and acknowledges that Arthrex owns and retains all right, title and interest in and to the SOS System and all improvements, modifications and derivative works of the foregoing, and all intellectual property rights in any of the foregoing. This Agreement does not transfer or grant to AOSSM or Participating AOSSM Member any rights with respect to the SOS System or with respect to any of such existing intellectual property rights, except as described in Section8.1 (License to Use SOS System).

#### 8. PUBLICATION AND LICENSES

**8.1** License to Use SOS System. Pursuant to the terms of each SOS Participation Agreement, Arthrex hereby grants to each Participating AOSSM Member a non-exclusive, non-transferable, royalty-free license to access and use the SOS System, in such AOSSM Member's Approved Jurisdiction only, for the purpose of entering, storing and accessing AOSSM Member Data and for the purposes of accessing and using the AOSSM Program Dataset and Combined Global Dataset, in each case in accordance with Applicable Laws, this Agreement, any applicable SOS Program Agreement and other professional and ethical rules to which such Participating AOSSM Member is subject. This license does not permit any Participating AOSSM Member to publish or disclose information owned by Arthrex or considered Arthrex Confidential Information. This license shall terminate upon termination of this Agreement.

Each AOSSM Party agrees not to (a) modify, adapt, alter, translate, or create derivative works from the SOS System; (b) sublicense, lease, rent, loan, or otherwise transfer access to the SOS System to any third party; (c) use the SOS System in any service bureau or time-sharing arrangement; (d) reverse engineer, decompile, disassemble, or otherwise attempt to derive the source code for the SOS System; or (e) otherwise use the SOS System except as expressly allowed under this Agreement.

**8.2 Publications, Generally.** Information entered into the SOS System about a Participating AOSSM Member's Data Subjects is at the discretion of the applicable Participating AOSSM Member. Each AOSSM Party agrees to acknowledge Arthrex in all publications and presentations of any such AOSSM Member Data or the AOSSM Program Dataset, and any such publications and presentations must document in the materials and methods section that SOS was used to collect AOSSM Member Data and the AOSSM Program Dataset. Each AOSSM Party is responsible for following all applicable industry rules and ethical standards governing publication authorship.

### 9. WARRANTIES, EXCLUSIVE REMEDIES AND DISCLAIMERS

**9.1 Warranties.** Each party warrants that it has full authority to enter into this Agreement. Each party warrants that it is not bound by any contractual or legal restrictions that would keep it from fulfilling its obligations under this Agreement.



**9.2** Arthrex Warranties. Arthrex does not warrant that the SOS System will operate uninterruptedly or error-free. Each AOSSM Party is solely responsible for the accuracy and adequacy of the information and data furnished for processing with the SOS System. To the extent that data is being transmitted over the Internet hereunder, each AOSSM Party acknowledges that Arthrex has no control over the functioning of the Internet and Arthrex makes no representations or warranties of any kind regarding the performance of the Internet. The successful operation of the SOS System is dependent on Participating AOSSM Member's use of proper procedures and systems and input of correct data.

**9.3 Disclaimer.** EXCEPT AS EXPRESSLY PROVIDED HEREIN, NEITHER PARTY MAKES ANY WARRANTIES OF ANY KIND, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, QUIET ENJOYMENT OR DATA ACCURACY TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW.

## **10. MUTUAL INDEMNITY**

Indemnification by Arthrex. Arthrex shall defend each of AOSSM and the Participating AOSSM 10.1 Members (each an "AOSSM Party" and collectively, "AOSSM Parties") against any claim, demand, suit or proceeding made or brought against an AOSSM Party by a third party alleging that the use of the SOS System as permitted hereunder infringes or misappropriates the intellectual property rights of a third party or violates Applicable Law (an "Arthrex Indemnified Claim"), and shall indemnify the applicable AOSSM Party for any damages, attorney fees and costs finally awarded against AOSSM Parties as a result of, and for amounts paid by AOSSM Parties under a court-approved settlement of, a Arthrex Indemnified Claim; provided that such AOSSM Party (a) promptly gives Arthrex written notice of the Arthrex Indemnified Claim, (b) gives Arthrex sole control of the defense and settlement of the Arthrex Indemnified Claim (provided that Arthrex may not settle or defend any Arthrex Indemnified Claim unless it unconditionally releases AOSSM Parties of all liability), and (c) provides to Arthrex all reasonable assistance, at Arthrex's expense. In the event of a Arthrex Indemnified Claim, or if Arthrex reasonably believes the SOS System may infringe or misappropriate the intellectual property rights of a third party, Arthrex may in its discretion and at no cost to AOSSM Parties (i) modify the SOS System so that it no longer infringes or misappropriates, without breaching Arthrex's warranties above, (ii) obtain a license for the AOSSM Parties' continued use of the SOS System in accordance with this Agreement, or (iii) terminate the Designated AOSSM Member's license to the SOS System upon 30 days' written notice.

**10.2** Indemnification by AOSSM Parties. The AOSSM Parties shall defend Arthrex against any claim, demand, suit or proceeding made or brought against Arthrex by a third party alleging that the AOSSM Member Data, any SOS System Data, the AOSSM Program Dataset or any AOSSM Parties' use of the SOS System, infringes or misappropriates the intellectual property rights of a third party or violates Applicable Law (a "AOSSM Indemnified Claim"), and shall indemnify Arthrex for any damages, attorney fees and costs finally awarded against Arthrex as a result of, or for any amounts paid by Arthrex under a court-approved settlement of, a AOSSM Indemnified Claim; provided that Arthrex (a) promptly gives AOSSM written notice of the AOSSM Indemnified Claim, (b) gives AOSSM sole control of the defense and settlement of the AOSSM Indemnified Claim unless it unconditionally releases Arthrex of all liability), and (c) provides to AOSSM all reasonable assistance, at AOSSM's expense.

**10.3** Exclusive Remedy. This "Mutual Indemnification" section states the indemnifying party's sole liability to, and the indemnified party's exclusive remedy against, the other party for any type of claim described in this section.



## 11. LIMITATION OF LIABILITY

**11.1 Limitation of Liability.** NEITHER PARTY'S LIABILITY WITH RESPECT TO ANY SINGLE INCIDENT ARISING OUT OF OR RELATED TO THIS AGREEMENT (WHETHER IN CONTRACT OR TORT OR UNDER ANY OTHER THEORY OF LIABILITY), THE PROGRAM, OR ANY SOS PARTICIPATION AGREEMENT SHALL EXCEED THE AMOUNT PAID HEREUNDER IN THE 12 MONTHS PRECEDING THE INCIDENT, PROVIDED THAT IN NO EVENT SHALL EITHER PARTY'S AGGREGATE LIABILITY ARISING OUT OF OR RELATED TO THIS AGREEMENT (WHETHER IN CONTRACT OR TORT OR UNDER ANY OTHER THEORY OF LIABILITY) EXCEED THE TOTAL PROGRAM AMOUNT PAID HEREUNDER. ANY ACTION BY EITHER PARTY MUST BE BROUGHT WITHIN ONE (1) YEAR AFTER THE CAUSE OF ACTION IS KNOWN TO HAVE ARISEN BY THE PARTY ASSERTING SUCH CLAIM.

**11.2** Exclusion of Consequential and Related Damages. IN NO EVENT SHALL EITHER PARTY HAVE ANY LIABILITY TO THE OTHER PARTY FOR ANY LOST PROFITS OR REVENUES OR FOR ANY INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES HOWEVER CAUSED, WHETHER IN CONTRACT, TORT OR UNDER ANY OTHER THEORY OF LIABILITY, AND WHETHER OR NOT THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THE FOREGOING DISCLAIMER SHALL NOT APPLY TO THE EXTENT PROHIBITED BY APPLICABLE LAW.

#### **12. TERM AND TERMINATION**

**12.1** Term. The term of this Agreement shall commence on the Effective Date and shall continue in effect until termination in accordance with Section 12.2 (the "Term").

**12.2** Termination. This Agreement may be terminated: (1) by any Party without cause upon thirty (30) calendar days prior written notice; and (2) for a material breach of this Agreement.

**12.3** Effect of Termination. Immediately upon receipt of a notice of termination of this Agreement, Participating AOSSM Member shall stop using the SOS System to enter, store and access AOSSM Member Data, and, when applicable, AOSSM Program Datasets and the Combined Global Dataset. After termination of this Agreement, no Participating AOSSM Member would have a right to participate in SOS as a healthcare provider or facility under the Program; such Participating AOSSM Member would be required to independently subscribe to SOS at the then-prevailing market rate and execute a SOS Participation Agreement. Termination of this Agreement by any Party shall not affect the rights and obligations of the Parties accrued prior to the effective date of the termination.

12.4 Survival. Sections 4, 5, 6, 7, 8, 9, 10, 11, 12.3, 12.4 and 13 shall survive termination of this Agreement.
13. MISCELLANEOUS

**13.1** Notice. Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is (A) delivered by hand or (B) received by Registered or Certified Mail, postage prepaid, return receipt requested, or received by facsimile and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

If to Arthrex: Arthrex, Inc. 1370 Creekside Blvd. Naples, FL 34108 Attn: OrthoIllustrated Surgical Outcome System



## If to AOSSM:

**13.2** Governing Law & Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws and regulations of the state of Florida, without regard to any choice of law principles that would apply the laws of any other jurisdiction. The Courts of Collier County have legal jurisdiction.

**13.3 Publicity & Use of Names.** The use by any Party of the name, trademark, trade name, logo, or any adaptation thereof, of any other Party in any publication, press release, advertisement, announcement, promotional material, or promotional activity relating to SOS requires the prior written consent of the other Party.

**13.4.** Entire Agreement; Modifications. This Agreement together with all attachments and exhibits constitutes the entire agreement and understanding between the parties and supersedes any prior or contemporaneous negotiations, agreements, understandings, or arrangements, of any nature or kind, with respect to the subject matter herein. This Agreement may be amended only by the mutual written consent of each Party.

**13.5** Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which together shall be one document binding on each Party and shall be considered delivered by each Party to the other Party upon transmission by facsimile or attachment to an email.

**13.6** Assignment. No AOSSM Party may assign or transfer any of its rights or obligations under this Agreement without the prior written consent of Arthrex. Any assignment not permitted hereunder shall be null and void.

**13.7** Relationship of the Parties. No AOSSM Party a partner, agent, employee, representative, or joint-venturer of Arthrex. Except as set forth in this Agreement, no Party, or its employees, agents, or subcontractors, has any right or authority to bind or act on behalf of the other Party.

**13.8** Severability. The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision of this Agreement.

**13.9** Waiver. No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of the same term, provision or condition, or of any other term, provision, or condition of this Agreement.

**13.10** Force Majeure. Arthrex will not be responsible for any failure to perform its obligations under this Agreement due to unforeseen circumstances or to causes beyond its control, including acts of nature, war, riot, embargoes, acts of civil or military authorities, earthquakes, fire, floods, accidents, strikes, shortages of transportation facilities, fuel, energy, labor, or materials, failures of telecommunications or electrical power supplies, or performance (or nonperformance) of common carriers, the U.S. Postal Service, or third-party courier services, and Arthrex will be relieved from its performance of such obligations to the extent, and for the duration, that such performance is prevented by such events.

[Signature Page Follows]



**IN WITNESS WHEREOF**, the parties hereto have caused their duly authorized representatives to execute this Agreement as of the date first written above.

# ARTHREX INC.

By:\_\_\_\_\_

John W. Schmieding Senior Vice President, General Counsel

American Orthopaedic Society for Sports Medicine

By:\_\_\_\_\_



# ADDENDUM A

### **Grant Agreement**

This non-binding pledge agreement (the "Agreement") is made this \_\_\_\_\_ day of \_\_\_\_\_, 2018, by and between Arthrex, Inc., a Delaware corporation (the "Pledgor"), and \_\_\_\_\_\_ (the "Pledgee"). This Agreement shall be effective immediately upon the date that it is countersigned by Pledgee (the "Effective Date").

WHEREAS, the Pledgor is a privately held medical device manufacturer dedicated to providing the finest quality products and educational services to meet the special needs of orthopedic surgeons and their patients, and the Pledgor's goals include the development of products for arthroscopic and minimally invasive orthopedic surgical procedures, as well as the development and refinement of surgical techniques to make technically demanding surgical procedures easier, safer and reproducible;

WHEREAS, the Pledgee qualifies as a public charity under sections 509(a)(1) or 509(a)(2) of the Internal Revenue Code of 1986, as amended (the "Code"), and the grant shall be used exclusively for charitable, educational or scientific purposes within the meaning of section 501(c)(3) of the Code;

WHEREAS, the grant request was unsolicited by Pledgor, was initiated and prepared by Pledgee alone, was submitted by Pledgee to Pledgor for review, and was submitted, reviewed, and approved by the Pledgor's grants committee in accordance with Pledgor's applicable policies and procedures;

WHEREAS, the purpose of the grant is to support and advance research, education and training in the field of least invasive orthopedic surgery by the support of a clinical fellow(s) at the Pledgee's facility;

WHEREAS, the grant will be used solely to support a clinical fellow(s) of the Pledgee's choosing who will be participating in an approved American Academy of Orthopedic Surgeons fellowship teaching/accreditation program.

WHEREAS, the grant presents opportunities for significant community educational and research benefits through the training, study and development of a fellow in orthopedic surgical procedures;

NOW THEREFORE, in consideration of the grant and the covenants, agreements and promises hereunder set forth, the Pledgor and the Pledgee agree as follows:

1. The pledge set forth in this Agreement is a **non-binding** obligation of the Pledgor. This Agreement shall not require the Pledgor, or any third party, to make any payments to the Pledgee and the Pledgee shall not rely on any potential payment.

2. Pledgor and Pledgee agree that the purpose of the Grant is in support of the benchmark analysis of SOS data\_\_\_\_\_\_ and that all system usage is awarded under the Grant shall be used only in a manner that is consistent with the purpose of the Grant, as set forth in this Agreement.

3. Pledgor and Pledgee agree that the Grant request was unsolicited by Pledgor, was initiated and prepared by Pledgee alone, and was submitted by Pledgee to Pledgor for review. Pledgor further acknowledges and agrees that the Grant request was submitted, reviewed, and approved by the Pledgor's grants committee in accordance with Pledgor's applicable policies and procedures.

4. Any Grant awarded pursuant to this Agreement shall be subject to and made in accordance with any and all applicable statutory, regulatory, and administrative health care Grant requirements, including, but not limited to, the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and any state anti-kickback laws, and shall be used by the



Pledgee exclusively for the purposes set forth herein. The parties further agree that the Grant awarded pursuant to this Agreement shall comply with the Advanced Medical Technology Association Code (commonly referred to as the "AdvaMed Code"). The Pledgor and the Pledgee agree that (i) the Grant contemplated under this Agreement is not intended as a reward or inducement for the purchase, ordering, or referral of the Pledgor's products or services, (ii) nothing in this Agreement shall require either party to refer business to the other party or take into account the volume or value of referrals, and (iii) no remuneration has been solicited or received for the furnishing, arranging or recommending of the purchase, lease or ordering of any goods or services reimbursable under state or federal health care programs.

5. The Pledgee shall have the right and discretion to select the recipients of any fellowship awards, without input from the Pledgor.

6. The Agreement shall commence on the Effective Date and shall terminate on the later of one year from the Effective Date or the termination of the fellowship program funded as the purpose of this Grant.